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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,274	02/09/2004	Yong Liang Chu	3781-009-27	8563

7590 05/10/2005

Supervisor, Patent Prosecution Services
PIPER RUDNICK LLP
1200 Nineteenth Street, N.W.
Washington, DC 20036-2412

EXAMINER	
MOSHER, MARY	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,274	CHU ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *15-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7-12-04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, claims 1-14 in the reply filed on 2/28/2005 is acknowledged. The traversal is on the ground(s) that examination of all the claims would not pose an undue burden. This is not found persuasive because the different classification of the three groups is a prima facie showing of burdensome divergent search.

The requirement is still deemed proper and is therefore made FINAL.

Priority

On the first page of the specification, there is a statement of related applications , but there is no claim for benefit under 35 USC §120 or §119(e). Is this correct?

If applicant desires benefit of a previously filed application under 35 U.S.C. 120 or 199(e), specific reference to the earlier filed application must be made in the instant application. **For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications**. This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition

should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Specification

A substitute specification was filed October 13, 2004; however, it was not accompanied by a statement regarding new matter and it did not show the changes made as required by 37 CFR 1.125. Therefore, for purposes of examination, the substitute specification has not been entered, and examination has been based upon the specification as filed and as amended on July 12, 2004.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of copending Application No. 10/860485. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the same assay using the same peptide sequence and the same hyaluronic acid bioconjugate.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13-14 lack antecedent basis for "the secondary antibody" in parent claim 1. Should they depend from claim 4?

Claim construction

In making the following rejections, the term "bioconjugate" is seen as encompassing any covalent linkage between polypeptide and polysaccharide, as indicated for example on specification page 7 lines 9-11. The term "hyaluronic acid analogue" is seen as encompassing any gycosaminoglycan polymer, as indicated on specification page 12 lines 10-13.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipate by Takacs et al (Journal of Interferon and Cytokine Research 19:781-789, 1999). Takacs teaches detection of antibody using a peptide conjugated to the polysaccharide carboxymethyl dextran on a solid support, thereby meeting each and every limitation of the claims.

Claims 1-5, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Saunders et al US 5,208,166. Saunders teaches an immunoassay where a solid support is coated with the hyaluronic acid analog chitosan, the chitosan is activated to covalently bind a polypeptide thereby forming a bioconjugate, and then an analyte is bound and detected. See Example 1 for a working example meeting the limitations of these claims; see also column 3, lines 1-23, column 4, lines 28-52.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saunders et al US 5,208,166. The teachings of Saunders are discussed above. Saunders does not explicitly discuss an ELIZA plate as the solid substrate, or discuss

the "sandwich" assay format required in claims 9-11, 13-14, or discuss placing plural conjugates at different locations on the solid support. However, Saunders clearly teaches use of chondroitin-polypeptide conjugates in the immunoassay art, immunoassays, and ELIZA plates, sandwich assays, and arrays were all well known features of immunoassays at the time the instant invention was made. Therefore, the invention as a whole is prima facie obvious, absent unexpected results.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saunders et al US 5,208,166 as applied to claims 1-5 and 8 above, and further in view of Pert et al EP 02249394. This claim differs from Saunders in specifying the polypeptide attached to the solid support. Pert teaches a peptide identical to SEQ ID NO:1, see page 8, and explicitly suggests its use in an immunoassay, see page 11. Therefore it would have been obvious to choose this peptide for use in the immunoassay broadly taught by Saunders, with reasonable expectation of success.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saunders et al US 5,208,166 as applied to claims 1-5 and 8 above, and further in view of Herold US 20050002953. This claim differs from Saunders in specifying the polypeptide attached to the solid support. Herold teaches that SARS coronavirus S proteins comprising SEQ ID NO:2, see Figure 4C residues 451-467. Herold also teaches expression vectors which make recombinant S protein. Herold teaches that, for a related coronavirus, the infected host produces antibodies primarily against the S protein. Therefore, the SARS S protein is an obvious choice for a polypeptide attached to a solid support in an immunoassay, for the purpose of detecting anti-SARS

antibodies made by an infected host. Therefore it would have been obvious to choose this peptide for use in the immunoassay broadly taught by Saunders, with reasonable expectation of success.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5/6/05

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER